IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
Civil Action No. 7:08-CV-00130-FL

VICTOR BROWN AND MARTHA BROWN, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	)	NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF MOTION IN LIMINE TO EXCLUDE CERTAIN INADMISSIBLE CORPORATE DOCUMENTS

INTRODUCTION

Defendant Novartis Pharmaceuticals Corporation ("NPC") respectfully submits this motion *in limine* to exclude, in whole or in part, certain documents that NPC expects Plaintiffs likely will attempt to introduce or discuss at trial. The documents and subject matters at issue consist primarily of e-mail communications that involve NPC employees. They are not relevant under Fed. R. Evid. 401.

To the extent that these documents are of any marginal relevance to this litigation, such relevance is greatly outweighed by the undue prejudice and jury confusion they are likely to create. Accordingly, these documents should also be excluded pursuant to Fed. R. Evid. 403. NPC thus seeks an order precluding Plaintiffs from introducing or discussing these documents at any time in front of the jury.

STATEMENT OF FACTS

The eleven documents at issue fall into three categories. The first category includes two documents that were created in 2003, after Mr. Brown commenced bisphosphonate therapy. The

second category includes eight documents that were created between 2003 and early 2005, after Mr. Brown had developed exposed bone in his jaw in May 2003, the beginning of his alleged osteonecrosis of the jaw ("ONJ"). Health Care Record of 5/19/03 (0099-0003-0004) (Ex. 1). The third category includes one additional document that was created in June 2005, i.e., after Mr. Brown became aware of the alleged association between ONJ and treatment with bisphosphonates in April 2005 and after his oncologist stopped his bisphosphonate therapy. Health Care Record of 4/25/2005 (0069-0020) (Ex. 2); Health Care Record of 4/21/2005 (0192-0655) (Ex. 3).

ARGUMENT

The specific NPC corporate documents discussed below have no relevance to issues to be determined by the jury or would create undue prejudice and confusion even if marginally relevant.

I. CORPORATE DOCUMENTS POST-DATING MR. BROWN'S INITIAL PRESCRIPTION ARE IRRELEVANT TO THE ISSUES IN THIS ACTION.

The two documents from early 2003 are irrelevant, created over six years after Mr. Brown commenced Aredia® therapy, and over a year after he commenced Zometa® therapy. Accordingly, they have no tendency to make any fact that is of consequence more or less likely for this matter and should be excluded under Fed. R. Evid. 401 and 402. Because of the danger that the corporate records will unfairly prejudice the jury, the documents also are inadmissible under Fed. R. Evid. 403.

A. January 29, 2003 E-mail from Epstein to Reinhardt (NJZAEM-00047909-47) (Ex. 4)

In this e-mail, David Epstein, CEO of NPC, discusses a Japanese study involving dosing regimens for zoledronic acid (the active ingredient in Zometa®) for patients with Paget's disease and osteoporosis, stating that "[a] 2mg dose in Japan runs the risk that physicians start to use

2mg in malignant disease cutting our revenue in half. If that dose was to bleed into other markets, the global impact on sales could be very large." Plaintiffs likely will attempt to use this document to argue that NPC was less concerned about safety than it was about profit.

This e-mail is unduly prejudicial, has limited probative value, and should be excluded. First, the e-mail has nothing to do with ONJ. Second, the Japanese study at issue does not involve patients with multiple myeloma, like Mr. Brown, or any metastatic disease but instead addresses osteoporosis and Paget's disease. Deposition Transcript of David Epstein, 255:23-256:24, Feb. 9. 2010 (excerpts attached as Ex. 5). Accordingly, it has no relevance to the adequacy of NPC's labeling for Zometa® in the United States or any relation to Mr. Brown's jaw problems. The e-mail should be excluded under Fed. R. Evid. 401. Even if the e-mail has nominal probative value, however, the likelihood of undue prejudice greatly outweighs such value. The e-mail therefore should also be excluded pursuant to Fed. R. Evid. 403.

B. May 5, 2003 E-mail from Fratarcangeli to Epstein et al. (ZAED 00079439-43) (Ex. 6)

The latest e-mail on this chain discusses NPC's planned response to initial reports of cancer patients receiving bisphosphonate therapy who developed osteonecrosis, including those discussed in a draft article by Dr. Salvatore Ruggiero.[1] The e-mail states, *inter alia*, "we'll try to avoid that the paper is ever published" and "[t]his could turn into a 'snow ball' effect with potentially some news noise." Plaintiffs likely will attempt to use the e-mail to speculate that NPC attempted to prevent the publication of this article.

Stefano Fratarcangeli, Novartis's Executive Director of Oncology Global Marketing for Zometa®, explained that he was hoping that the NPC medical team would "meet with Dr.

[1] Dr. Ruggiero is one of the early authors to publish articles regarding the alleged association between ONJ and treatment with bisphosphonates.

Ruggiero, review his reports, and, you know, listen to his point of view, state the oncology point of view -- he is a surgeon -- and hoping that there would be further scientific communication before that would bring to him to -- to have additional research before publishing his results." Deposition Transcript of Stefano Fratarcangeli, 163:11-23, May 22, 2008 (excerpts attached as Ex. 7). Of course, he noted "[t]here is no way you *can* prevent the publication of an article." *Id.* at 54:13-16 (emphasis added). Moreover, Dr. Ruggiero *did* publish his article, and Plaintiffs have no evidence that NPC actually tried to prevent its publication. Dr. Ruggiero testified that he did not know of anything that NPC had done to prevent the article's publication. Deposition Transcript of Salvatore Ruggiero, 47:23-48:2, May 12, 2008 (excerpts attached as Ex. 8).

The document is not relevant. Whether or not an individual employee of NPC speculated about the possibility that publication of a draft article might be delayed or prevented does not make more or less likely a material fact in this case, *e.g.*, the adequacy of the Aredia® and Zometa® labels. Accordingly, the e-mail should be excluded under Fed. R. Evid. 401.

In the event the Court finds any probative value in the e-mail, the e-mail should be excluded because its probative value would be greatly outweighed by the obvious inflammatory impact of the suggestion that NPC wanted to preclude publication of an article about its drug or the suggestion – which is not supported by the document in any event – that NPC in fact initiated any effort to prevent publication. Fed. R. Evid. 403.

II. CORPORATE DOCUMENTS POST-DATING MR. BROWN'S INITIAL PRESCRIPTION AND DEVELOPMENT OF HIS JAW PROBLEMS ARE IRRELEVANT TO THE ISSUES IN THIS ACTION.

There are eight corporate documents authored between 2003 and early 2005 that are irrelevant, created after Mr. Brown allegedly developed ONJ. Accordingly, the documents have no tendency to make any fact that is of consequence more or less likely for this matter and

should be excluded under Fed. R. Evid. 401 and 402. In additional, the documents also are inadmissible under Fed. R. Evid. 403 because of the danger that the corporate records will unfairly prejudice the jury.

A. June 20, 2003 E-mail from Goessl to Hei et al. (ZAEM-00133003) (Ex. 9).

This e-mail is from Dr. Carsten Goessl, a former Senior Clinical Research Physician for NPC. Dr. Goessl hypothesized potential mechanisms for the newly reported adverse event of jaw necrosis in Aredia® and Zometa® users, reviewing articles about oral manifestations of osteopetrosis, a genetic disease. The e-mail acknowledged a belief on Dr. Goessl's part that there could be a "possible" but unproven "link" between intravenous bisphosphonates and "orofacial osteonecrosis." At the end of the first paragraph, Dr. Goessl stated that "the thoughts do rather indicate than disprove a relation . . . . . sorry." Plaintiffs likely will attempt to portray this sentence as a concession of general causation, even though the e-mail itself reiterates the unproven nature of any causal relationship.

The e-mail should be excluded under Fed. R. Evid. 401. It retrospectively considers potential mechanisms for how bisphosphonates might cause ONJ, but talks only in terms of hypotheses, not proven scientific fact and not even in terms of reasonable degree of scientific certainty. Moreover, it addresses a genetic disease that Mr. Brown did not have. The speculations of Dr. Goessl in this e-mail do not make more or less likely that Mr. Brown's condition was caused by his bisphosphonate use. Even if marginally relevant for some purpose, however, the e-mail will unduly confuse the jury given that it bears on a condition that Mr. Brown did not have. Fed. R. Evid. 403.

B. July 10, 2003 E-mail from Goessl to Hei (ZAEM-00077111) (Ex. 10).

This e-mail from Dr. Goessl – continuing to investigate the potential connection between NPC's bisphosphonates and ONJ – provides brief summaries of three articles discussing jaw

abnormalities. Dr. Goessl noted that there was no reference to "chemotherapy-induced jaw/facial [ostenecrosis]" in an article by Dr. Winquist and added: "(= appears to be very rare with chemotherapy alone)." Plaintiffs may use this e-mail to suggest that Dr. Goessl reached his own scientific/medical conclusion that jaw abnormalities were very rare in patients on chemotherapy.[2]

If the Winquist article itself is relevant, Plaintiffs can use it at trial as they would use any other scientific article, *e.g.*, under Fed. R. Evid. 803(18), if the proper foundation is laid. However, Dr. Goessl's commentary is not relevant. The e-mail makes no material fact more or less likely and should be excluded under Fed. R. Evid. 401. Moreover, even if minimally relevant for some reason, the likelihood of confusion greatly outweighs such relevance. Therefore, the e-mail should be excluded under Fed. R. Evid. 403.

C. December 1, 2003 E-mail from Linguri to Dunsire et al. and attached agenda for upcoming Osteonecrosis Advisory Board (ZAEM-01199529-32) (Ex. 11).

This e-mail transmits a draft internal agenda for NPC's initial Advisory Board in December 2003, a meeting that brought together outside oncologists and oral and maxillofacial surgeons to elicit their views on ONJ in patients treated with Zometa® or Aredia®. NPC prepared the draft agenda months after it had changed the Zometa® warnings to reflect the appearance of ONJ cases, but NPC had continued to investigate the potential link.

The objectives listed on the draft focus on attempting to better understand various aspects of the role bisphosphonates may be playing regarding ONJ, including the possibility of "[g]ain[ing] agreement that osteonecrosis of the jaw pre-existed bisphosphonates and can be caused by a multitude of factors in patients with and without cancer." Plaintiffs will speculate

[2] Plaintiffs did not question Dr. Goessl about this e-mail at his deposition and thus has no evidence concerning his 2003 opinions on the frequency of osteonecrosis ("ON") associated with chemotherapy.

that this draft constituted a "secret" agenda and that the Advisory Board process was illegitimate because the agenda ultimately distributed to the participants did not contain that objective.

The Advisory Board proceedings had nothing to do with how Mr. Brown was treated. NPC's duty to warn ran only to Drs. Hunter and Arb, and neither has indicated any awareness of the Advisory Board proceedings. Accordingly, Fed. R. Evid. 401 should preclude any use of this draft agenda. In the event that any minimal relevance can be shown, the document should be excluded under Fed. R. Evid. 403 because the likelihood of confusion – *i.e.* speculation about motives, intent, and the reasons for changes to the final agenda – would greatly outweigh such relevance.

D. January 18, 2004 Letter from Klein to Dunsire (ZA-0525027) (Ex. 12).

This is an unsolicited letter from a sales representative (Samuel Klein) to Dr. Deborah Dunsire, Vice President, Novartis Oncology and head of the cross-disciplinary team working on reports of ONJ. In the letter, Mr. Klein states:

> I have enclosed some internet postings regarding ONJ. Some of this is quite interesting and may even help identify potential "enemies and allies."
>
> Dr. Fedele of Italy seems to express some very level headed thoughts regarding this matter.

Plaintiffs may argue that this letter establishes that NPC was seeking to identify "enemies and allies." However, the out-of-court statement is inadmissible hearsay, subject to no exception to the hearsay rule. Fed. R. Evid. 802. It is not an admission by NPC because Mr. Klein, a sales representative, was not an NPC decision maker, was not authorized to make any statements on the subject, and was addressing a matter not within the scope of his employment.[3] There is no

[3] Mr. Klein testified that he did not typically write letters to people in higher positions at NPC. Deposition Transcript of Samuel Klein, 260:18-21, Aug. 7, 2009 (excerpt attached as Ex. 13).

showing that his job description – promotion of NPC drugs pursuant to their labels – involved writing such letters back to NPC executives, checking the internet for postings on ONJ, or otherwise inserting himself into business strategy decisions taking place well over his level of responsibility. The letter therefore cannot be considered as constituting an admission by NPC.

Additionally, the letter is not relevant. It does not bear on the adequacy of NPC's warnings for Aredia® or Zometa® nor on whether Drs. Hunter and Arb would have acted differently had the labeling been different. Because it does not make any material fact in the case more or less likely, it should be excluded under Fed. R Evid. 401.

Finally, the letter's admission into this case will be unduly inflammatory, given that it improperly suggests NPC was involved in a process of identifying "enemies and allies." Therefore, even if marginally relevant for some reasons, it should be excluded under Fed. R. Evid. 403.

E. March 12, 2004 e-mail from Weiss (ZAEM-00824590) (Ex. 14).

In this e-mail, Ms. Weiss, a former NPC Senior Medical Information Specialist, discusses the number of osteonecrosis of the jaw ("ONJ") cases in Aredia® and Zometa® users reported to NPC at that time. Ms. Weiss states that she "would be extremely cautious about using numbers [of case reports] with any of our customers" and that NPC should "implicate the risk factors as much as possible e.g. radiotherapy, chemotherapy, dental procedures, etc." when conferring with prescribing oncologists. *Id.* NPC anticipates that Plaintiffs will improperly use this e-mail to imply that NPC hid information about the number of ONJ case reports from oncologists and obscured the risk of ONJ by referring to other risk factors. *See* Tr. of Closing Argument in *Fussman v. Novartis Pharms. Corp.*, 1:06-CV-149, at 7:16-20 (M.D.N.C., Nov. 18, 2010) (plaintiff's counsel displaying e-mail and claiming that "[l]ater on [NPC] know[s] about multiple

cases and again instead of being frank and honest when people inquire they say let's tell them about the risk factors, be careful about using any numbers") (Ex. 15).

The Court should exclude this e-mail as irrelevant because there is no evidence that any NPC sales representative or other employee ever discussed ONJ risk factors, or the numbers of ONJ cases, with Drs. Hunter or Arb, Mr. Brown's prescribing oncologists, and because Plaintiffs cannot show that the adverse drug experiences ("ADEs") referred to in the e-mail were substantially similar to the adverse event occurring in Mr. Brown.[4] To the extent that there is any marginal relevance, such relevance is greatly outweighed by the likelihood of undue confusion. Fed. R. Evid. 403.

F. May 12, 2004 E-mail from Schubert to Hoff et al. (ZAEM-00860680-81) (Ex. 16).

Dr. Mark Schubert's e-mail discusses suggested edits to a *draft* of a "White Paper" regarding ONJ, the final version of which NPC issued in June 2004. The White Paper, *Expert Panel Recommendations for the Prevention, Diagnosis, and Treatment of Osteonecrosis of the Jaws: June 2004* (hereinafter "White Paper") (Ex. 17), was the product of two NPC Advisory Boards, co-authored by external advisors, including Drs. Ruggiero, Marx,[5] and Schubert. Dr. Schubert, in discussing what risk factors for exposed jaw bone should be mentioned in the White Paper, noted that the inclusion of too long a list of other risk factors would "have the appearance of 'blowing smoke.'" Plaintiffs likely will use this e-mail concerning the draft to imply that the

[4] *See also* NPC's Memorandum in Support of Motion *in Limine* to Exclude Inadmissible Evidence Concerning Dissimilar Adverse Drug Experience Reports (filed December 2, 2011).

[5] Dr. Marx is one of Plaintiffs' experts in the case, opining solely on general causation, not on what actually caused Mr. Brown's alleged ONJ-related jaw problems.

list of risk factors for ONJ included in the final version of the White Paper was over-inclusive and inaccurate. The e-mail should be excluded for the following reasons:

First, the letter is not relevant. It does not bear on whether Drs. Hunter and Arb would have acted differently had the Zometa® labeling been different. It should thus be excluded under Fed. R. Evid. 401. Second, any possible relevance is undermined because the final version of the White Paper *did* reflect Dr. Schubert's comments on the draft. The final White Paper not only notes that "[t]he precise risk factors for osteonecrosis of the jaws have not been identified," but also identifies only six possible risk factors. White Paper at 2. The White Paper goes on to provide a much longer list of "[o]ther risk factors that have been previously identified for osteonecrosis (not limited to the jaws)." *Id.* The final version of the White Paper is consistent with the comments provided by Dr. Schubert in his e-mail concerning the draft White Paper and Dr. Schubert signed off on the final version. *See* White Paper at 4. Thus, there is no probative value to this third-party e-mail, and it would be offered solely for its inflammatory nature. It should therefore be excluded under Fed. R. Evid. 401 and 403.

G. May 28, 2004 E-mail from Schubert to Hei (ZAEM-00217697-700) (Ex. 18)

This document is another e-mail from Dr. Schubert in which he states, among other things, that NPC does not want to be perceived to "blow smoke" in how the White Paper discusses other risk factors. Plaintiffs will misuse this e-mail in the same way and for the same purpose as plaintiffs have the May 12, 2004 e-mail addressed in Part H. above. Therefore, the e-mail should be excluded for the same reasons as described above in Part H. It is not relevant to any of the issues in this litigation.

H. January 31, 2005 E-mail from Petraglia to Hei et al. (ZAEM-01790080-82) (Ex. 19).

This e-mail chain discusses an alleged "discrepancy" between the number of adverse events reported to FDA and the number of adverse event reports received by NPC. Plaintiffs will use this e-mail chain to imply incorrectly that NPC failed to file reports of adverse events to FDA. This e-mail should be excluded because it is irrelevant to the issues in this litigation under Fed. R. Evid. 401.

Any possible relevance is undermined by the fact that the reason for the alleged "discrepancy" is completely benign. Once NPC listed ONJ in the Adverse Event sections of its labels for Aredia® and Zometa®, NPC was no longer required to file a report of an additional ONJ adverse event within 15 days. *Compare* 21 C.F.R. § 314.80(a) (defining "[u]nexpected adverse drug experience" as "[a]ny adverse drug experience that is not listed in the current labeling for the drug product"), (c)(1)(i) (requiring reporting of "serious and unexpected" adverse drug experiences within "15 calendar days of initial receipt of the information"), *with* 21 C.F.R. § 314.380(c)(2)(ii) ("The applicant shall report each adverse drug experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of approval of the application, and then at annual intervals."). At the time of this e-mail, some reports of ONJ had not yet been submitted to FDA because ONJ already appeared on the label and the periodic report to FDA was not yet due.[6] Thus, this e-mail does not demonstrate that

[6] *See* Deposition Transcript of Dr. Dionigi Maladorno, 304:17-306:19, March 19, 2008 (excerpts attached as Ex. 21) (explaining that cases were pending submission to FDA in a "periodic report" and that the discrepancy between NPC's and FDA's figures was resolved); January 31, 2005 E-mail from Carol Pamer (FDA) to Annemarie Petraglia (NPC) (ZA-0705033-34) (attached as Ex. 22) ("… the reports were sent in via Periodic reports rather than Expedited to AERS [the FDA adverse event database]. Therefore, these reports are not in the AERS database at present.").

NPC failed to comply with any reporting requirements.[7] The introduction of this e-mail would create undue prejudice and needlessly confuse the jury on an issue with, at best, nominal relevance. It should thus be excluded under Fed. R. Evid. 403.

III. CORPORATE DOCUMENTS POST-DATING MR. BROWN'S AND HIS ONCOLOGIST'S AWARENESS OF THE ALLEGED ASSOCIATION ARE IRRELEVANT TO THE ISSUES IN THIS ACTION.

A document from June 2005 was written long after Mr. Brown commenced Aredia® and Zometa® treatments and after he first was diagnosed with necrotic bone. It has no relevance to the adequacy of the label of Aredia® and Zometa® at the time he was receiving Zometa® or to whether his treatment would have been any different if the label were different. Further, Mr. Brown's oral surgeon noted in his records that he discussed the association between bisphosphonates and ONJ with Mr. Brown on April 25, 2005. *See* Ex. 2. Mr. Brown's prescribing oncologist, Dr. Arb, also stopped his Zometa® treatments. *See* Ex. 3. Documents that were created subsequent to Mr. Brown's and his prescriber's awareness of the alleged association will not make any fact material to Plaintiffs' failure-to-warn allegations more or less likely. Because they are irrelevant under Fed. R. Evid. 401-402 and are prejudicial under Fed. R. Evid. 403, the Court should exclude them.

A. June 15, 2005 E-mail from Sablinska to Cook (ZAEM-002131140-44) (Ex. 20).

This e-mail contains an exchange between Dr. Katarzyna Sablinska, the epidemiologist working on Zometa® for NPC in 2005, and Mr. Geoffrey Cook, NPC Director of U.S. Public Relations, regarding how to characterize risk factors for ONJ in a corporate communication not

[7] *See* Deposition Transcript of Plaintiff's Expert Suzanne Parisian, 374:23-375:7, April 16, 2009 (excerpts attached as Ex. 23) (admitting FDA never cited NPC for not reporting these Adverse Drug Experiences (ADEs) as 15-day reports); *see also id.* at 362:11-363:2 (admitting that NPC provided the ADEs to FDA), 364:4-13 (agreeing that manufacturers could submit labeled events in periodic reports instead of in 15-day reports under FDA regulations in effect at that time).

intended for physicians. In this e-mail chain, Dr. Sablinska agreed that most of the risk factors listed were "well established risk factors for [osteonecrosis]." Accordingly, she stated that "[t]hey are assumed to be also risk factors for ONJ" but noted that "there is very little well-documented knowledge regarding ONJ." She reiterated in the final e-mail of the chain that these things were "risk factors" for osteonecrosis generally.

Plaintiffs will offer this e-mail chain to argue that an NPC employee believed that the label as of September 2003 was misleading because "there [was] very little well-documented knowledge regarding ONJ." This e-mail chain should be excluded because it is not relevant. Fed. R. Evid. 401. It was written over eight years after Mr. Brown commenced his Aredia® therapy, over three years after he began Zometa® treatments, and over two years after he first developed necrotic bone.

Even if this e-mail chain had some marginal relevance, such relevance is outweighed by the undue prejudice it would engender. Plaintiffs' suggestion that this e-mail – which does not address the label – indicates a belief of Dr. Sablinska that the label was inadequate is unsupported by the e-mail itself or any other document. Because this implication would unduly prejudice NPC and unnecessarily confuse the jury, this e-mail chain should be excluded pursuant to Fed. R. Evid. 403.

CONCLUSION

For the foregoing reasons, the Court should grant this motion and exclude the noted documents.

Dated: December 2, 2011

Respectfully submitted,

/s/ Peter G. Pappas

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF MOTION IN LIMINE TO EXCLUDE CERTAIN INADMISSIBLE CORPORATE DOCUMENTS, using the CM/ECF system, which will send notification of such filing to CM/ECF participants:

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This the 2nd day of December, 2011.

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